OCT - 6 2000

K002110

V. 510(K) SUMMARY

510(K) Notification Summary For The Spine Cable System

ADMINISTRATIVE INFORMATION

Manufacturer Identification And Sponsor	Pioneer Surgical Technology 375 River Park Circle Marquette, Michigan 49855-1781 Telephone: (906) 226-9909 Facsimile: (906) 226-9932
Official Contact	Amy H. Mommaerts, Manager Regulatory Affairs
Date Prepared	July 10, 2000

DEVICE IDENTIFICATION

Proprietary Name	Spine Cable System
Common Name	Spine Cable System
Classification Name And Reference	Cerclage, Bone Fixation: CFR 888.3010
Devices on Which Substantial Equivalence Is Claimed	SONGER Cable System (K922952) SDB Cerclage System (K992616) Sofamor Danek Spinal System (K925812, K920201, K913735); and Stainless Steel wire manufactured prior to 1976.

Device Description

The Spine Cable System is a cerclaging implant construct comprised of a multi-strand cable with integral crimp (Please see *Appendix B: Engineering Drawings*). It is accompanied by surgical instrumentation for use: 1) a cable tensioner/crimper; 2) a torque driver; and 3) a cable cutter, 4) cable hook, 5) pretensioner

To use the device, the cable is passed around the bone and the free end of the cable is then passed through the integral crimp. The cable is tensioned using the tensioning/crimping instrument and tensioning tool. The excess cable is cut using the cable cutter and removed (Please see *Appendix A: Spine Cable Surgical Technique*).

Intended Use

The Spine Cable System is intended as a replacement for plain monofilament wire and may be used for three primary types of surgical applications:

1. Spinal Trauma - sublaminar, interspinous or facet wiring;
2. Spinal Reconstruction - spinal deformities, scoliosis, kyphosis and spondylolisthesis; and
3. Spinal Degenerative Surgery – as an adjunct to spinal fusions.

Technological Characteristic Compared to Predicate Device

The Spine Cable system is predicated on the following spinal cable systems SONGER Cable System (K922952) and the Sofamor Danek Spinal Cable Systems (K925812, K920201, K913735).

Performance Data

The instrumentation for the Spine Cable system uses similar instrumentation as the SONGER Cable System (K922952).

The implants of the Spine Cable system are similar to the implants of the Sofamor Danek Spinal Cable Systems (K925812, K920201, and K913735). The crimp is attached to the cable making it easier to handle, as there are no small loose crimp that can be lost or dropped. The attached crimp is able to rotate on the cable. This can decrease the stress on the cable as the crimp can rotate to a less severe angle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

Ms. Amy H. Mommaerts
Manager, Regulatory Affairs
Pioneer Laboratories, Inc.
375 River Park Circle
Marquette, Michigan 49855-0627

Re: K002110
Trade Name: SPL Crimp Sysytem
Regulatory Class: II
Product Code: JDQ
Dated: July 10, 2000
Received: July 12, 2000

Dear Ms. Mommaerts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): _____

DEVICE NAME: SPL Crimp System

INDICATIONS FOR USE:

The SPL Crimp is indicated as a replacement for monofilament wire in spinal applications and may be used anywhere monofilament wire has previously been indicated:

1. Spinal Trauma: For sublaminar, interspinous or facet wiring;
2. Spinal Reconstruction: To correct spinal deformities, scoliosis, kyphosis and spondylolisthesis; and
3. Spinal Degenerative Surgery: As an adjunct to spinal fusions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002110

Prescription Use _____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)